K020764

JUN 0 3 2002

510(k) Summary

Submitter:	Kinamed, Inc.
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Contact person:	Vineet K. Sarin, Ph.D.
Date prepared:	March 8, 2002
Trade name:	NaviPro™

Substantial equivalence claimed to: OrthoPilot® (K003347), also filed by Kinamed Inc.

Description:

NaviPro™ uses an optical localizing camera and infra-red reflective markers ("trackers") to track the spatial position of bones and medical instruments during hip replacement surgery. Measurements obtained from the system allow for intra-operative assessments of implant position and orientation.

Intended use:

NaviPro™ is a system for computer-aided navigation of surgical instruments whose purpose is to optimally position the acetabular shell during hip replacement surgery, and to report changes in rotational center, limb length, and femoral offset as a result of prosthetic implantation. The system aids the surgeon in accurately positioning the acetabular shell during hip replacement and provides intra-operative measurements of femoral position and orientation in relation to the pelvis.

Summary of technological characteristics:

NaviPro™ intra-operatively reports the position of the acetabular shell relative to the pelvis as well as the changed relationship between femur and pelvis as a result of joint replacement. The patient data needed to carry out this procedure is recorded intra-operatively. Pre-operative CT or fluoroscopic imaging is unnecessary. The link between patient and computer is established by infra-red reflective trackers that are securely attached to the patient. An infra-red localizing camera that is linked to the computer calculates the position and orientation of the trackers.

Surgical instruments, such as an acetabular shell impactor tool and a calibrated measurement probe, are also outfitted with infra-red trackers and can be brought into a spatial relationship with the patient. The NaviPro™ system requires only the information provided by the trackers to determine the orientation of the acetabular shell, as well as changes in limb length and femoral offset.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Vineet K. Sarin, Ph.D.
Director of Research and Development
Kinamed, Inc.
820 Flynn Road
Camarillo, CA 93012-8701

Re: K020764
Trade/Device Name: NaviPro
Regulation Number: 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: II
Product Code: HAW
Dated: March 7, 2002
Received: March 7, 2002

Dear Dr. Sarin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020764

Device Name: NaviPro™

Indications for Use:

NaviPro™ is a system for computer-aided navigation of surgical instruments whose purpose is to optimally position the acetabular shell during hip replacement surgery, and to report changes in rotational center, limb length, and femoral offset as a result of prosthetic implantation. The system aids the surgeon in accurately positioning the acetabular shell during hip replacement and provides intra-operative measurements of femoral position and orientation in relation to the pelvis. General spatial measurements may be made and recorded as deemed necessary by the surgeon user.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

Prescription Use X OR Over-the-Counter Use
(Per 21 CFR 801.109)

510(k) Number K020764